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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/500,531

06/30/2004

Shouqin Zhang

LUNGBJ/105/PC/US

4346

2543

7590

08/08/2006

EXAMINER

DAVIS, RUTH A

ALIX YALE & RISTAS LLP
750 MAIN STREET
SUITE 1400
HARTFORD, CT 06103

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 08/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/500,531

Applicant(s)

ZHANG, SHOUQIN

Examiner

Ruth A. Davis

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1 – 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method for extraction small molecules from biological materials. However, the specification fails to set forth a representative number of examples in order to reasonably verify possession of such a potentially enormous number of molecules.

The MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that the claims are broad generics, with respect to *all* molecules from all biological materials. The possible variations of small molecules are limitless. Although the specification has disclosed 3 molecules that could be extracted by the claimed method, such a disclosure is actually *very few* in number as compared to the enormous, *potentially millions* of types of small molecules which could be obtained from biological materials.

The MPEP states that the purpose of the written description requirement is to ensure that the invention had possession, as of the filing date of the application, of the specific subject matter

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later claimed by him or her. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F. 2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outline [goals] appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, the specification fails to provide adequate written description for the genus of 'small molecules from biological materials and does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the entire scope of the claimed invention at the time the application was filed. Thus, the written description requirement has not been satisfied.

3. Claims 1 – 17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for extracting flavonoids, polyphenols and baicalein from ginkgo leaves, tea leaves and Radix, respectively, does not reasonably provide enablement for a method for extracting small molecules from biological materials. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The claims are drawn to a method for extracting small molecular ingredients from biological materials under super high pressure. As such, the claims encompass a wide variety of molecules from an innumerable number of biological materials. However, the specification fails to teach one in the art how to practice the method with any biological material and any small molecule. High pressure treatment is commonly used in the food art to inactivate microorganisms and enzymes (biological materials) (see attached "High pressure treatment of

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foods”) and it is known in the art that high pressure treatment will inactivate prions (proteins) (see Brown et al.). Thus the state of the art suggests that applying super high pressure to some biological materials will in fact, damage the molecular structures of molecular components. Moreover, it would require an undue burden of experimentation for one in the art to determine what small molecular compounds could be successfully extracted from what biological materials, by applying super high pressure as claimed.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1 – 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and its dependents appear to be drawn to a method for extracting small molecular components, however are rendered vague and indefinite because the claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors. Examples of such include but are not limited to the following:

In claim 1, the phrases “small molecular ingredients”, “crashing”, “nonnal pressure” are rendered vague and indefinite because they are not adequately defined by the claim language or specification.

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In claim 1, the manner by which the claim is recited is confusing for including numerical steps, as it is confusing if these refer to claims numbers, or steps that are practice in the method.

In claim 1, the recitation of “the step of pretreatment”, “the step of closure”, “the step of increasing pressure”, “the step of holding pressure” and “the step of releasing pressure” is confusing, as it is unclear if the limitations following are intended to further describe these steps, or are mere suggestions.

In claim 1, line 4, “the raw material” lacks sufficient antecedent basis.

In claim 1, line 6, “the above mixture” and “the pressure container” lack sufficient antecedent basis.

In claim 2, the phrases “is firstly poured”, “after that”, “and then the pressure of the pressure container is increased via the medium” are confusing.

In claim 2, line 4, “the medium” lacks sufficient antecedent basis.

In claim 3, it is unclear if the step of increasing, holding and releasing pressure are each practiced by one or several steps, or if the steps are collectively accomplished by a single or multiple steps.

In claims 4 and 5, the phrase “which means that” renders the claims indefinite because the claims are required to specifically point out and distinctly claim the invention, not to further define what the claims may alternatively encompass. It is noted that the specification is the proper format to define terms of the claims.

In claim 6, the phrase “which refers to” rendered the claims indefinite and confusing.

In claim 6, the phrase “i.e. ” renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

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In claim 7, it is unclear if additional processing technologies are required to be practice, or if they are optional. It is further unclear what the processing technologies are meant to include.

In claim 8, “the said combination” lacks sufficient antecedent basis.

In claim 8, it is unclear what the phrase “assembling devices” refers. It is further unclear if such devices make up “the combination”, or if the “devices” are an additional construct of the method.

In claim 9, “the combination” lacks sufficient antecedent basis.

In claim 11, “the medium” lacks sufficient antecedent basis.

In claim 12 “the mixture of raw biomaterials” lacks sufficient antecedent basis.

In claim 13, it is unclear to what “the extraction under super high pressure” refers; for example the method or a resulting composition.

In claims 14 - 16, it is unclear if a heater and cooler is placed in a pressure container, or if the pressure container itself is heated and/or cooled.

Claim 15 fails to end with a period.

In claim 17, the term “charging” has not been adequately defined by the claim language or specification.

It is further noted that claims 8, 11 and 17 are so confusing, vague and indefinite that they have not been able to be interpreted by the examiner.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 1 – 3, 6, 10 – 12 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 04244203.

Applicant appears to claim a method for extracting small molecular components from biological materials, the method comprising crushing a biological material with a solvent; placing the resulting mixture into a container; increasing the pressure from normal to 100 – 1000MPa; holding the mixture under pressure for 3 – 30 minutes; and releasing the pressure to normal. The mixture is poured into an airtight packing container which is then placed into a pressure container; the steps of increasing, holding and releasing pressure are accomplished by a single or multiple steps; the multiple steps are accomplished by crushing the biological material with solvent and extracting under super high pressure, combining the resulting material with more solvent and extracting again under super high pressure; the solvent is water, an organic solvent or a mixture thereof and the biological material further comprises additives.

JP 04244203 teaches a method for extracting rice bran (biological material), wherein the rice bran is combined with amylase and a solvent and treated with 800MPa pressure for 60 minutes (abstract).

The reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1 – 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 04244203, JP 09140337 or JP 04256405.

Applicant appears to claim a method for extracting small molecular components from biological materials, the method comprising crushing a biological material with a solvent; placing the resulting mixture into a container; increasing the pressure from normal to 100 – 1000MPa; holding the mixture under pressure for 3 – 30 minutes; and releasing the pressure to normal. The mixture is poured into an airtight packing container which is then placed into a pressure container. The steps of increasing, holding and releasing pressure are accomplished by a single or multiple steps, specifically via ladder type or pulse type. The multiple steps are accomplished by crushing the biological material with solvent and extracting under super high pressure, combining the resulting material with more solvent and extracting again under super high pressure; the mixture obtained from the method can be further processed; the biological material can be pretreated; the solvent is water, an organic solvent or a mixture thereof; the biological material further comprises additives; the extraction is performed under heating or cooling and the pressure container is placed in a cooler.

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JP 04244203 teaches a method for extracting rice bran (biological material), wherein the rice bran is combined with amylase and a solvent and treated with 800MPa pressure for 60 minutes (abstract).

JP 09140337 teaches a method for extracting kombu seaweed (biological materials), wherein the seaweed is cut and combined with ionic water (or pretreated by crashing and formulation with a solvent); placed in a pressing vessel (the step of closure); and is placed under 50 – 200 MPa pressure (steps of increasing, holding, releasing pressure) (abstract).

JP 04256405 teaches a method for extracting biomass (biological material) comprising suspending the biomass (with a solvent) and treating with high pressure of more than 300 MPa, wherein the resulting product is further clarified.

The references do not teach that pressure is applied in the manner claimed, that the mixture is further processed, wherein the process occurs multiple times, or wherein heat or cooling is applied. However, at the time of the claimed invention, such steps were routinely practice in the art when extracting substances under high pressure. Thus, at the time the claimed invention was made, it would have been well within the purview of one of ordinary skill in the art to optimize the various parameters of the methods, to include the manner by which pressure is applied, how often and under cool/heated conditions, as a matter of routine experimentation.

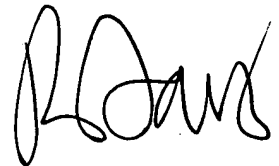
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 - 2:30pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ruth A. Davis
Primary Examiner
Art Unit 1651



August 3, 2006